

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON

SMITH & NEPHEW, INC. and
JOHN O. HAYHURST, M.D.,

No. CV 04-29-MO

Plaintiffs,

STATEMENT OF REASONS
SUPPORTING PERMANENT
INJUNCTION

v.

ARTHREX, INC.,

Defendant.

MOSMAN, J.,

On November 19, 2008, this Court issued an Order of Permanent Injunction in this action. The following is the Court's Statement of Reasons Supporting that Injunction.

A. Background

1. On January 12, 2004, plaintiffs Smith & Nephew, Inc. and Dr. John O. Hayhurst commenced this action against defendant Arthrex, Inc. for infringement of U.S. Patent No. 5,601,557 ("the '557 patent"). In their Complaint, plaintiffs requested an injunction to stop Arthrex's continued infringement. (Dkt. No. 1).

2. Dr. Hayhurst is the owner and Smith & Nephew is his exclusive licensee of the '557 patent. (Dkt. No. 1).

3. Following an initial trial which resulted in a hung jury, the issues of infringement,

willful infringement and damages were tried to a jury in a re-trial of this case from June 3, 2008, to June 11, 2008.

4. On June 11, 2008, the jury in the re-trial of this case returned a verdict of infringement in favor of the plaintiffs. (Dkt. No. 489).

5. Specifically, the jury found that Arthrex infringed claims 1 through 7 of U.S. Patent No. 5,601,557 (“the ‘557 patent”) by marketing and selling four suture anchors: 1) the Bio-SutureTak; 2) the PEEK SutureTak; 3) the PEEK PushLock; and 4) the Bio-PushLock. In addition, Arthrex’s infringement was found to be willful (see Dkt. No. 489).

6. Previously, this Court had dismissed, or Arthrex had abandoned, all of Arthrex’s invalidity and unenforceability defenses. (Dkt. No. 241; Dkt. No. 278).

7. Thus, the Court finds that the ‘557 patent is valid, enforceable and willfully infringed.

8. The jury also awarded the plaintiffs monetary damages in the amount of \$14,695,858. This included \$4,788,014 to compensate the plaintiffs for Smith & Nephew, Inc.’s lost profits for lost sales through the end of 2005 as a result of Arthrex’s infringement. (Dkt. No. 489).

B. The Patented Invention and Competition Between the Parties

9. The ‘557 patent is directed to certain methods of using a medical device called a suture anchor. Suture anchors allow a surgeon to repair soft tissue (such as ligaments, tendons or capsules) that has torn away from the bone, by re-attaching the tissue back to the bone so it can heal.

10. In about 1992, Dr. Hayhurst’s original exclusive licensee, Acufex Microsurgical Inc., began marketing and selling Dr. Hayhurst’s patented suture anchors, which were implanted using the claimed methods of the ‘557 patent. These licensed anchors were all plastic, and they all pushed in or tapped into a pre-drilled hole in the bone (Re-Trial Trans. p. 211, line 6 to p. 212, line 14, Dkt. No. 524, Exhibit 2; Mahoney Decl., Dkt. No. 523, ¶ 4).

11. Smith & Nephew acquired Acufex and thereby became Dr. Hayhurst's exclusive licensee. (Re-Trial Trans. p. 212, lines 15-17, Dkt. No. 524, Exhibit 2).

12. Arthrex introduced its first suture anchor in 1996 or 1997 (Re-Trial Trans. p. 800, line 22 to p. 801, line 5, Dkt. No. 524, Exhibit 2).

13. The original Arthrex anchors fell into a different market niche than Dr. Hayhurst's plastic, push-in anchors. Arthrex's initial anchors, called FASTak, were metal, and they were screwed into the bone (Re-Trial Trans. p. 259, line 19 to p. 260, line 10, Dkt. No. 524, Exhibit 2).

14. Arthrex's screw-in anchors were not very successful. By 1999, Arthrex was still at the "bottom of the pack," according to Arthrex's marketing witness at the re-trial, William Benevitz (Re-Trial Trans. p. 766, lines 3-8, Dkt. No. 524, Exhibit 2).

15. To change that, Arthrex began making plastic, push-in suture anchor products. In the year 2000, Arthrex did not have any of that part of the market (Re-Trial Trans. p. 810, lines 5-13, Dkt. No. 524, Exhibit 2).

16. Arthrex introduced its first infringing anchor, the plastic, push-in Bio-SutureTak, in late 2001. (Re-Trial Exhibit 175, Dkt. No. 524, Exhibit 3; Re-Trial Trans. p. 742, line 7 to p. 743, line 24, Dkt. No. 524, Exhibit 2).

17. At the time of such introduction, Arthrex was already aware of the '557 patent. This awareness was at the highest level of the company, including by its President Reinhold Schmieding. (Re-Trial Exhibit 175, Dkt. No. 524, Exhibit 3; Re-Trial Trans. p. 742, line 7 to p. 745, line 4, Dkt. No. 524, Exhibit 2).

18. Arthrex credits the Bio-SutureTak with turning around its fortunes in the suture anchor market.

19. The other major designs in addition to the Bio-SutureTak included Arthrex's other three plastic, push-in anchors that were also found to infringe: the PEEK SutureTak; the PEEK PushLock; and the Bio-PushLock anchors.

20. Two of Arthrex's three largest selling suture anchors today are the infringing

Bio-SutureTak and the infringing PushLock anchors, according to Arthrex's Mr. Benavitz (Re-Trial Trans. p. 767, line 24 to p. 768, line 1, Dkt. No. 524, Exhibit 2).

21. Along with the anchors, Arthrex produced and distributed surgical instructions showing how its infringing anchors could be used to repair exactly the same dislocated shoulder injury (Bankart lesion) for which Dr. Hayhurst had made his invention in the first place (see Re-Trial Exhibits 26, 27 and 42, Dkt. No. 524, Exhibits 4-7; Re-Trial Trans. p. 194, lines 6-25, Dkt. No. 524, Exhibit 2).

C. Irreparable Harm

22. The first factor in determining whether to award an injunction is to determine whether there would be irreparable harm without an injunction.

23. Arthrex is Smith & Nephew's biggest competitor for suture anchors throughout the United States (Re-Trial Trans. p. 265, lines 2-8, Dkt. No. 524, Exhibit 2).

24. The actual competition between Arthrex and Smith & Nephew is in a specific segment of that market – plastic, push-in anchors – which Dr. Hayhurst and his licensees, Acufex and Smith & Nephew, created, and which Arthrex has now taken over as a result of its ongoing infringement of Dr. Hayhurst's '557 patent.

25. When Arthrex gained market share, it did so by taking that market share from other competitors, including Smith & Nephew and the plaintiffs' other licensee, Johnson & Johnson (Mitek) (Re-Trial Trans. p. 765, line 22 to p. 766, line 19, Dkt. No. 524, Exhibit 2).

26. Smith & Nephew continues to market the Acufex suture anchors implanted by Dr. Hayhurst's patented method, and has invested significant time, money and effort in developing an additional suture anchor, called the BioRaptor, which is also covered by Dr. Hayhurst's patents and implanted by the methods covered by his '557 patent. (Mahoney Decl., Dkt. No. 523, ¶¶ 4, 5, and 7).

27. The new Smith & Nephew BioRaptor was introduced to the market in late 2004 (Re-Trial Trans. p. 734, lines 3-17, Dkt. No. 524, Exhibit 2; Mahoney Decl., Dkt. No. 523, ¶ 5).

The BioRaptor is also a plastic, push-in anchor, and it comes pre-loaded with a suture and mounted on its own installation tool (Re-Trial Trans. p. 271, line 3 to p. 272, line 21, Dkt. No. 524, Exhibit 2).

28. In addition, since that time, Smith & Nephew has continued to invest substantial time and money in developing still other plastic, push-in anchors. These include the KINSA anchor which was introduced in the fall of 2006, and the BioRaptor 2.3 PK and Footprint PK anchors, both of which were introduced in early 2008. Including the BioRaptor, Smith & Nephew has invested approximately \$4 million in development costs for these new anchors. (Mahoney Decl., Dkt. No. 523, ¶¶ 5, 6, 7).

29. In terms of product-to-product competition, Smith & Nephew's BioRaptor suture anchor matches up almost exactly with Arthrex's Bio-SutureTak. Both the Bio-SutureTak and the BioRaptor are made of bio-absorbable plastic, and both are push-in anchors. Both include pre-attached sutures, and both anchors are pre-mounted on installation tools. Further, both are sold for the same surgeries. (See, e.g., Re-Trial Trans. p. 271, line 6 to p. 272, line 21, p. 706, line 24 to p. 707, line 10, and p. 734, line 20 to p. 735, line 2, Dkt. No. 524, Exhibit 2).

30. This identity of form and function between the BioRaptor and Bio-SutureTak was the basis for Smith & Nephew's lost profits claim at the re-trial (Re-Trial Trans. p. 703, line 24 to p. 705, line 11 and p. 706, line 24 to p. 707, line 15, Dkt. No. 524, Exhibit 2), and the evidence on this issue was not challenged by Arthrex, either in cross-examination of Smith & Nephew's expert, Richard Troxel (see Re-Trial Trans. p. 734, line 18 to p. 739, line 1, Dkt. No. 524, Exhibit 2), or in the examination of its own damages expert, Russell Parr (Re-Trial Trans. p. 1089, lines 3-7; p. 1093, lines 5-18, Dkt. No. 524, Exhibit 2).

31. The jury found, as a fact, that Smith & Nephew had lost almost \$5 million in sales of its BioRaptor suture anchor in a little over a year, from late 2004 when the BioRaptor was introduced through the end of 2005, as a result of Arthrex's infringement (see Re-Trial Exhibit 130, Exhibit D, Dkt. No. 524, Exhibit 9).

32. Arthrex continues to be Smith & Nephew's major competition in the plastic push-in anchor market, and Smith & Nephew continues to lose BioRaptor sales as a result of Arthrex's ongoing infringement (Mahoney Decl., Dkt. No. 523, ¶¶ 11, 12).

33. Due to Arthrex's infringement, Smith & Nephew cannot sell the BioRaptor suture anchor as extensively as it could if the infringement was not ongoing (Mahoney Decl., Dkt. No. 523, ¶¶ 4, 7 and 11).

34. Arthrex's infringement is ongoing, including after 2005 and even after the jury's verdict in this case, and therefore Smith & Nephew has lost additional sales after 2005 to Arthrex and continues to lose sales to Arthrex.

35. These lost sales translate into lost market share in the suture anchor market for Smith & Nephew.

36. Smith & Nephew's lost sales extend beyond that of the suture anchors themselves, as Smith & Nephew and Arthrex both also sell drills, drill guides and other associated products for use with their suture anchors (Mahoney Decl., Dkt. No. 523, ¶ 12).

37. The loss of sales of such other associated products was an unchallenged factor in the plaintiffs' expert setting the reasonable royalty damages rate at the re-trial (Re-Trial Trans. p. 719, line 18 to p. 720, line 4, Dkt. No. 524, Exhibit 2; Re-Trial Exhibit 130, Exhibit D, Dkt. No. 524, Exhibit 9), which rate the jury adopted.

38. Thus, Arthrex's continuing infringement also costs Smith & Nephew its profits and market share from these additional, related products.

39. The plaintiffs have licensed Johnson & Johnson under the '557 patent. Johnson & Johnson's Ethicon division (formerly Mitek) pays the plaintiffs an ongoing royalty on its sales of its licensed anchors. (Re-Trial Trans. p. 721, lines 7-24, Dkt. No. 524, Exhibit 2).

40. Arthrex's infringing suture anchors have allowed Arthrex to displace Johnson & Johnson (Mitek) as the market leader and greatly reduce Johnson & Johnson's market share (Re-Trial Trans. p. 766, lines 3-16, Dkt. No. 524, Exhibit 2).

41. Any such reduction in Johnson & Johnson's market share also reduces the royalties paid to the plaintiffs under this license and represents a further harm in the form of ongoing loss of income to the plaintiffs as a result of Arthrex's infringement.

42. In addition to new product development, in 2004, Smith & Nephew began investing millions of dollars in clinical marketing and surgeon education to try to recapture and increase market share (Re-Trial Trans. p. 257, line 5 to p. 258, line 13, Dkt. No. 524, Exhibit 2).

43. But Smith & Nephew had a difficult time trying to make any inroads against Arthrex. In fact, third party marketing reports indicate that with Arthrex's big "lead" in this market, Smith & Nephew was not making much progress (Re-Trial Trans. p. 735, line 18 to p. 736, line 2, Dkt. No. 524, Exhibit 2; Mahoney Decl., Dkt. No. 523, ¶¶ 8, 9, 10; Re-Trial Exhibit 134B, Dkt. No. 524, Exhibit 8).

44. Thus, Arthrex, due to its infringement, now has such a large piece of the suture anchor market and is so firmly entrenched in it that Smith & Nephew's efforts to increase market share, despite its investment of millions of dollars in additional marketing efforts, and new product introductions, have largely been unsuccessful.

45. Arthrex's leading position in the suture anchor market was obtained, at least in part, by its willful infringement of the '557 patent.

46. Smith & Nephew's predecessor company, Acufex, marketed the first plastic, push-in suture anchors, and Smith & Nephew itself has spent a great deal of money in bringing new suture anchors to the market. (Mahoney Decl., Dkt. No. 523, ¶ 6).

47. Arthrex's reputation as the market leader and as an innovator in the suture anchor market was built largely on the infringing suture anchors. This has directly detracted from Smith & Nephew's reputation as an innovator in the marketplace.

48. As a result of Arthrex's infringement, it appears to others as if it is Arthrex that is the "innovator" in the suture anchor market instead of Smith & Nephew.

49. Arthrex's infringement has harmed Smith & Nephew's reputation as an innovator in the suture anchor market.

50. Arthrex's continued infringement will result in substantially reduced sales revenue for Smith & Nephew, as well as lost market share, lost investment in new product development, lost sales of collateral products and licensing revenue, and loss of reputation, customer relationships and goodwill.

51. Irreparable harm exists in this case, since the infringement is by a direct competitor and the infringement has caused the patentee to suffer losses of sales, market share, investment in new product development, sales of collateral products, licensing revenue, reputation, customer relationships and goodwill.

52. In view of all of the foregoing, the Court finds that the irreparable harm factor is clearly established.

D. Adequacy of Monetary Relief

53. The second factor in determining whether to award an injunction is whether money damages would be inadequate. This factor is closely related to the irreparable harm factor discussed above.

54. Arthrex and Smith & Nephew are major competitors in the market for plastic press-in suture anchors.

55. The plaintiffs cannot quantify the damage they will incur, particularly in terms of lost market share, lost reputation and lost customer relationships and goodwill, if forced to continue to share the '557 technology with Arthrex for the remainder of the '557 patent's life.

56. It is not Smith & Nephew's general policy to grant licenses to competitors. (Re-Trial Trans. p. 723, lines 13-15, Dkt. No. 561, Exhibit 1).

57. The license that Smith & Nephew granted to Ethicon in 2002, in settlement of a prior patent infringement lawsuit, does not demonstrate that monetary relief is adequate. The Ethicon license includes restrictions on the types of suture anchors that Ethicon can sell, which

precludes suture anchors like Arthrex's. (See Re-Trial Trans. p. 722, lines 8-13, Dkt. No. 561, Exhibit 1). In addition, the Ethicon license was granted in 2002, before Smith & Nephew introduced the BioRaptor suture anchor, and so at the time of the Ethicon license Smith & Nephew was not in the same competitive position as it now is with Arthrex.

58. Accordingly, the Court finds that monetary damages are insufficient to adequately compensate Smith & Nephew for the lost market share, lost business opportunities, and damage to reputation customer relationships and goodwill described above.

59. Thus, this factor also favors an injunction.

E. Balance of Hardships

60. The third factor in determining whether to award an injunction involves assessing the balance of hardships.

61. Arthrex started its infringing activities with full knowledge at the highest level of the company, including by its President Reinhold Schmieding, of the '557 patent. (Re-Trial Exhibit 175, Dkt. No. 524, Exhibit 3).

62. Despite such knowledge, Arthrex went ahead with its infringing activities (Re-Trial Exhibit 175, Dkt. No. 524, Exhibit 3).

63. Arthrex ultimately took a position at trial that it was not relying on an advice-of-counsel defense. It presented no other evidence of good faith. The jury found the infringement willful.

64. Arthrex cannot now claim hardship because it elected to ignore the '557 patent in the first place without the benefit of any reliable opinion of counsel.

65. By its willful infringement, Arthrex has improperly benefited for about seven years, to the direct detriment of the patentee and his licensee, Smith & Nephew.

66. While there will be some impact on Arthrex's business, Arthrex was well aware of that risk when it started to and continued to market the accused products from 2001 until even today.

67. Arthrex is a large company, which operates worldwide and had U.S. sales in fiscal year 2008 of about \$444M. (Benavitz Decl., Dkt. No. 545, ¶ 7).

68. Arthrex describes itself as having locations worldwide and over 3000 products (Arthrex website, Dkt. No. 524, Exhibit 10).

69. The issuance of a permanent injunction in this case will not even come close to driving Arthrex out of business.

70. An injunction would not even drive Arthrex out of the suture anchor business because Arthrex continues to sell non-infringing suture anchors.

71. In terms of the practical effect of the injunction on the marketplace, the injunction will only impact Arthrex's SutureTak family of anchors (consisting of the Bio-SutureTak and PEEK SutureTak anchors).

72. The injunction will not have the effect of removing Arthrex's PushLock anchors from the market, since Arthrex changed the design of those anchors during the course of this lawsuit. Instead, the PushLock anchors that are currently on the market are the subject of a new lawsuit, Smith & Nephew, Inc. v. Arthrex, Inc., Civil Action No. 08-00714-MO.

73. Arthrex's U.S. sales of suture anchors in its SutureTak family in fiscal year 2008 were about \$38.6 million. (See Troxel Decl. filed Nov. 17, 2008, Dkt. No. 602, ¶ 6). Given that Arthrex's total U.S. sales over that time period amount to \$444 million, this represents about 8.7% of Arthrex's U.S. sales. (See Id. at ¶¶ 4-6).

74. Thus, an injunction in this case will not impose any unreasonable hardship on Arthrex.

75. On the other hand, the burden on Smith & Nephew, if an injunction does not issue, will be far greater than any harm to Arthrex.

76. Smith & Nephew has experienced over seven years of infringement by Arthrex.

77. Without an injunction, other competitors may feel free to infringe the '557 patent.

78. Without a permanent injunction, Smith & Nephew will continue to suffer lost

sales, lost market share, lost investment in new product development, lost sales of collateral products, lost licensing revenue, lost reputation, and lost customer relationships and goodwill.

79. These harms significantly tip the balance of hardships in favor of the plaintiffs.

80. Thus, the Court finds that the balance of harms factor supports grant of a permanent injunction.

F. The Public Interest

81. The final factor in determining whether to award an injunction is determining where the public interest lies.

82. First of all, the Court recognizes that there is substantial public interest in enforcing valid patents, and this public interest favors the grant of an injunction.

83. Arthrex's customers, the surgeons and their patients, will not be harmed by an injunction because there are a variety of other acceptable substitute anchors available, as its expert, Mr. Parr, suggested (Parr Expert Report at pages 7, 9, Dkt. No. 524, Exhibit 11; Re-Trial Trans. p. 1316, line 10 through p. 1318, line 6, Dkt. No. 524, Exhibit 12).

84. Arthrex's damages expert, Mr. Russell Parr, took the position with Arthrex's approval, that the surgeons are completely indifferent to which anchor they use (Parr Expert Report at pages 7, 9, Dkt. No. 524, Exhibit 11; Re-Trial Trans. p. 1316, line 10 through p. 1318, line 6, Dkt. No. 524, Exhibit 12).

85. Arthrex itself has admitted that there are many available substitute anchors on the market. In its Opposition to Plaintiffs' Motion for Permanent Injunction, Arthrex admitted that there are many other acceptable suture anchors on the market that surgeons can select in order to replace the SutureTak and PushLock anchors:

If forced to do without the benefits of the PushLock anchors or SutureTak anchors, a surgeon could turn to anchors made by Ethicon, Linvatec, Arthrocure, Biomet and Arthrotek. These companies all offer anchors that a surgeon would find at least as desirable, if not more, to the Smith & Nephew BioRaptor and are useable for the same surgeries as Arthrex's SutureTak and PushLock anchors.

(Arthrex Br., Dkt. No. 543, at 5).

86. Arthrex also submitted a declaration from its expert, Dr. Greenleaf, who is an orthopedic surgeon, which includes the very same admission. (Greenleaf Decl., Dkt. No. 547, ¶ 8).

87. Arthrex's expert, Dr. Burkhead, who is also an orthopedic surgeon, testified at his deposition that if a surgeon could not use the Bio-SutureTak anchor, that surgeon would be able to instead use "metal anchors that are very reliable and have been used for years." Dr. Burkhead also testified that he personally "would probably go back to the Mitek G2 because I know it is relatively inexpensive and consistently works." (See Burkhead Dep. at p. 284, lines 3-19, attached as Exhibit 2 to Legaard Decl. filed Nov. 17, 2008, Dkt. No. 596).

88. Smith & Nephew suture anchors are also available on the market and can be substituted for Arthrex's SutureTak anchors. For example, as set forth above, Smith & Nephew's BioRaptor suture anchors are comparable to Arthrex's Bio-SutureTak anchors.

89. As set forth above, the jury found as a fact that Smith & Nephew has lost sales of its BioRaptor anchors to Arthrex's infringing anchors. Necessary to and implicit in that finding is the fact that such anchors may be used as substitutes for each other.

90. In fact, during the permanent injunction hearing of October 28, 2008, Arthrex's counsel admitted that the jury's verdict on lost profits damages, which has been upheld by this Court, was conclusive on the issue that Arthrex's infringement took sales directly from Smith & Nephew due to the infringing features. (Tr. of Inj. Hrg. of 10/28/08, at 31-32, attached as Exhibit 1 to Legaard Decl. filed Nov. 17, 2008, Dkt. No. 596).

91. In addition, Smith & Nephew has the capacity to increase suture anchor production to more than meet all the demands for the enjoined anchors (O'Connor Decl., Dkt. No. 522, ¶¶ 4, 7).

92. As set forth above, due to changes in their design, this injunction will not impact the versions of the Arthrex PushLock anchors that are currently on the market.

93. Accordingly, the Court finds that there would be either no or minimal adverse effect on surgeons or patients as a result of the injunction.

94. Thus, the Court finds that the public interest factor also supports granting a permanent injunction in this case.

IT IS SO ORDERED.

DATED this 3rd day of December, 2008.

/s/ Michael W. Mosman
MICHAEL W. MOSMAN
United States District Judge